# EANM Position on the Proposal for a Biotech Act I

The nuclear medicine community welcomes the European Biotech Act I (the Act) as a key initiative to strengthen Europe's leadership in biotechnology and enhance the EU's clinical research ecosystem through an evidence based and risk-proportionate regulatory approach.

Nuclear medicine is a specialised medical field that uses radiopharmaceuticals, which are radioactive compounds designed to selectively localise in specific tissue types to diagnose, treat, and monitor a wide spectrum of diseases. Each year, approximately 10 million nuclear medicine procedures are performed across Europe. The main clinical application is oncology, but major applications are also found in cardiology and in neurology; both adult and paediatric patients benefit from the diagnostic and therapeutic capability of the discipline. **Nuclear medicine enables earlier diagnosis, precision treatment and personalised therapeutic approaches, thereby contributing to improved patient outcomes and quality of life** (see our Overarching Narrative).

According to a JRC study,[i] **the number of patients eligible for radioligand therapies[ii] is expected to increase significantly in the coming years**. However, European healthcare systems and nuclear medicine institutions are not yet adequately equipped to accommodate the growing demand. At the same time, increasing global competition in biotechnology and clinical research highlights the need for coordinated EU action to strengthen Europe's attractiveness for radiopharmaceutical clinical trials, support innovation capacity, and ensure patient access to advanced nuclear medicine diagnostics and therapies.[iii]

**Many concepts and proposals of the Act, including the promotion of strategic projects, regulatory simplification, innovation support mechanisms, and targeted funding instruments, are positive and could significantly strengthen the European biotechnology ecosystem.** These measures are also highly relevant for nuclear medicine, which represents an increasingly important area of precision medicine and theranostic innovation[iv]. However, nuclear medicine is based on the use of radiopharmaceuticals, which are medical products with unique properties (e.g., short shelf life) and challenges, including time-sensitive production and distribution, decentralised manufacturing, and the interaction with radiation protection and Euratom-related regulation. **A supportive regulatory framework is pivotal in ensuring that nuclear medicine practice and research can flourish and reach as many patients as possible.** The proposals below aim to ensure that the Biotech Act can reach its full potential and be fit for purpose also when it comes to nuclear medicine health biotechnology.

The proposed amendments to the Clinical Trials Regulation (CTR), particularly the establishment of minimal-intervention clinical trials, are vital improvements to reduce regulatory burdens that might otherwise hinder nuclear medicine development without significantly improving patient safety. However, **the Act needs to be fit for purpose also for the nuclear medicine sector, as studies involving radiopharmaceuticals need to comply with additional obligations, and are often imaging based.** High regulatory burdens otherwise risk patient access to innovative treatments. In addition to revising specific provisions to ensure that nuclear medicine studies can benefit from streamlined regulatory pathways where appropriate, **the recitals should explicitly reference**


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**diagnostic and imaging nuclear medicine studies, and accompanying guidance should clarify how the Regulation applies to these studies**.

**Main recommendations**

To ensure that the Biotech Act reaches its full potential and delivers on equitable access to innovative treatments for patients, the EANM respectfully urges the co-legislators to include the following points during the legislative process:

- First, the recitals should clarify that medicinal products such as radiopharmaceuticals fall within the scope of health biotechnology and are eligible for strategic project recognition. Without this clarification, project promoters and Member State authorities will face legal uncertainty that undermines the Act's innovation objectives from the outset.
- Second, the risk-based approach for minimal-intervention and low-intervention clinical trials must be further clarified to address the realities of radiopharmaceutical research. The Act's stated commitment to proportionate regulation will ring hollow for nuclear medicine if simplified approaches remain unclear, thereby hindering the approval of innovative radiopharmaceuticals and nuclear medicine procedures.
- Third, the Act must acknowledge the fact that clinical trials for some products, such as radiopharmaceuticals, need to comply with additional legislation, in this case with the EURATOM Directive. Streamlined procedures must therefore apply without prejudice to, and in coordination with, EURATOM research exposure authorisation requirements and the additional steps needed for authorisation of such trials should be taken into account.

## 1. Including guidelines for definitions (Chapter I)

For nuclear medicine, clarification is needed regarding the definition of health biotechnology and the connected eligibility for designation as a strategic project, as some radiopharmaceuticals sit in a grey area between being included in Biotechnology and falling out of scope.

A radiopharmaceutical has two functional components: a targeting molecule, which seeks out and binds to specific tissues or cells in the body, and a radioactive atom attached to it, which either emits a detectable signal for imaging or delivers a localised dose of radiation for treatment. The Act's definition of health biotechnology centres on the use of living organisms or biological materials to produce medical products. Whether a given radiopharmaceutical falls within that definition, therefore, depends on the nature of its targeting molecule.

Some targeting molecules are unambiguously biological in origin: antibodies, proteins, and certain peptides derived from or modelled on natural biological structures. Radiopharmaceuticals built on these molecules clearly qualify as biotechnology products under the Act. Others are purely synthetic chemicals with no biological derivation and would equally clearly fall outside the Act's scope. The difficulty lies in the large and growing middle ground: many modern radiopharmaceuticals use small synthetic molecules that closely mimic biological ligands, or hybrid constructs in which the targeting component is biological, but the radioactive label is attached through a chemical process. Under the Act's current wording, it is not clear whether these products qualify, and reasonable experts could


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reach different conclusions. This ambiguity creates a real and practical risk: project promoters, hospital-based radiopharmacies, and national authorities in different Member States may interpret eligibility for strategic project designation inconsistently, undermining both innovation investment and regulatory predictability across the EU.

A further complication is that nuclear medicinal products frequently do not fit neatly into a single regulatory category. A theranostic agent may simultaneously constitute a medicinal product, incorporate a device component, and rely on AI-based software to guide dosing decisions. No single regulatory framework currently governs such combinations in their entirety, and the Act does not address this.

**EANM therefore calls for two targeted clarifications. First, the Commission should issue a practical guidance document with worked examples illustrating how the definition of health biotechnology applies to specific radiopharmaceutical product types. Second, the Act should acknowledge that theranostic agents straddling multiple regulatory frameworks may require coordinated assessment pathways and should provide a mechanism to facilitate this.**

## 2. Clarifying strategic projects, support, and mapping (Chapters II and III)

The Strategic Projects framework and related support and funding structures offer considerable potential for nuclear medicine, particularly for cyclotron networks and radiopharmacy infrastructure supporting theranostic drug development. However, the Act's framing appears to be mainly oriented toward large-scale biomanufacturing and does not take account of nuclear medicine biotechnology. Radionuclide production[v] is inherently distributed and small-scale due to the short physical half-lives of most radionuclides – a cyclotron site supplying a regional network is structurally very different from a conventional biomanufacturing plant, but no less strategically important. **To address this, the criteria for Strategic Project recognition should be clarified to explicitly accommodate distributed production models, as well as regional radiopharmacy networks, including hospital-based facilities.**

### a. Taking specific supply chain dependencies into account

Strengthening industrial capacity and reducing dependencies on third countries is particularly relevant for medical radionuclides and radiopharmaceutical precursors, because the EU is structurally vulnerable when it comes to radionuclides such as Mo-99/Tc-99m (small number of ageing reactors), Lu-177 (concentrated supply, surging clinical demand from radioligand therapies), and Ac-225 (severely constrained globally). Without secure supply, the AI and theranostic ambitions of the Act cannot deliver in nuclear medicine. **Therefore, specific characteristics and supply-chain dependencies of the nuclear medicine sector need to be taken into account in the recognition and support of industrial capacity related strategic projects.**

### b. Radiation safety and radiopharmaceutical handling infrastructure are essential

**Strategic infrastructure projects should also recognise radiation safety and radiopharmaceutical handling infrastructure as essential components of innovation capacity in nuclear medicine.** Infrastructure needed for radiation protection may not be sufficiently considered within this category of strategic project, despite being indispensable for the safe development and deployment of radiopharmaceuticals. Such technology includes shielding infrastructure, radioactive waste management systems, contamination monitoring, occupational dosimetry, ventilation systems, and environmental monitoring capabilities.



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### c. Including clinician-scientist career pathways and measuring AI literacy

**To address talent and skills needs, the workforce architecture must account for clinician-scientist career pathways, in addition to industry and academia.** For many products, the principal route by which new developments are brought into clinical use safely is through clinician-scientists. Hospital-based work needs a protected time or career structure, cross-border mobility for clinical specialists must be addressed, and the role of clinical specialists in the safe deployment of health biotechnology must be recognized.

Additionally, clinical AI literacy and the operationalization of AI-enabled medical products for clinical specialties is absent from the proposal, despite clinical specialists being the primary developers and deployers of such technology. **Clinical literacy gaps must be measured alongside industrial workforce gaps as part of the European Commission's strategic mapping, as this materially determines whether AI products are developed and used safely.**

### d. Recognising radiation protection regulation and authorities

There are several aspects particular to nuclear medicine that should be considered regarding support for strategic projects and strategic mapping. **First, accelerated and streamlined permitting procedures under the Biotech Act should not weaken radiation protection oversight or reduce compliance with the Euratom Directive and the Basic Safety Standards Directive. Second, the European Commission should rely on the expertise of radiation protection authorities for strategic mapping and coordination efforts, which would be particularly relevant for theranostics and decentralised radiopharmaceutical manufacturing.** The mapping should further include the medical radioisotope[vi] value chain, particularly because there is a need for more coherence between the different initiatives under the Euratom framework.

## 3. Clarifying 'one manufacturing step in the EU' for SPC (Chapter IV)

The proposed one-year SPC extension for products manufactured (at least in part) in the EU and tested in multi-country clinical trials is a welcome incentive for innovation. For nuclear medicine, this could be particularly beneficial for theranostic pairs where the therapeutic and diagnostic components are developed in parallel. It should, however, be **clarified how the 'one manufacturing step in the EU' requirement can be satisfied, and if steps later in the process, such as radiolabelling in the EU, would suffice.**

It should further be noted that for some radiopharmaceutical products, such as paediatrics, the practical value of this incentive may be more limited than for other health biotechnology, because of small patient populations and short product lifecycles. The Act could therefore consider complementary incentives and support mechanisms for radiopharmaceuticals developed for rare diseases or oncological conditions, including for example fee reductions, priority assessment, and a European-level coordination mechanism for paediatric data pooling.

## 4. Making AI and data as biotechnology enablers fit for purpose (Chapter VI)

**The European Medicine Agency (EMA) guidance on the deployment and use of systems based on advanced technologies should specifically include guidance on:**

- **AI in radiopharmaceutical development (target identification, ligand design);**
- **AI-based dosimetry, which is essential for radioligand therapy authorisation;**
- **AI-derived imaging biomarkers used as endpoints in clinical trials; and**

- **theranostic pairing of diagnostic and therapeutic agents.**

This is needed because radiopharmaceuticals raise distinctive AI-related questions that general medicinal-product guidance will not address.

Many of the Act's goals would benefit from mandating the use of FAIR data practices (meaning that data should be findable, accessible, interoperable, and reusable), a principle which comes from the broader EU data strategy. Mention and integration of FAIR principles in the Act would make the innovation goals more robust without being overly prescriptive, as the detailed implementation would still sit in the European Health Data Space (EHDS). **Therefore, the Act could include a provision stating that data generated under it should adhere to FAIR principles where appropriate.**

**High impact health biotechnology strategic projects in the form of trusted testing environments should include nuclear medicine equivalents to wet-labs and Advanced Therapy Medicinal Products (ATMPs),** such as imaging-based testing environments with capacity across different scanner brands, to ensure that such technologies can receive support. Similarly, the concept of biotechnology data quality accelerators needs to be adjusted so that it can be applied to nuclear medicine. Most health data systems such as the EHDS focus on electronic health records and clinical data, not on quantitative imaging. Molecular imaging datasets (PET[vii], SPECT[viii], quantitative imaging) have distinct harmonisation challenges related for example to scanner physics and limited cross-manufacturer comparability. Biotechnology data quality accelerators should be aligned with imaging-specific standards and note should be taken of the distinct harmonization challenges.

It should further be noted that some nuclear medicine health biotechnology, such as Zr-89 tracers, are administered in relatively high effective doses, inherently limiting the subject numbers in such studies. Furthermore, some diseases with a strong focus on nuclear medicine in their treatment, such as neuroendocrine tumours, are rare. **It should therefore be kept in mind that acquiring large datasets in nuclear medicine is challenging, potentially affecting applications such as AI training.**

## 5. Involving nuclear medicine professionals and experts (Chapter VII)

### a. Foresight Panel

The Foresight Panel's role in horizon-scanning and regulatory preparedness is highly relevant to nuclear medicine, where new targeting molecules are entering clinical practice rapidly. **Nuclear medicine, radiopharmacy, and radiation medicine expertise should be explicitly represented in the Panel's composition, either as standing members or as regularly invited external experts.** The current draft refers to experts from EMA, Substances of Human Origin, Medical Device Coordination Group, and Health Technology Assessment bodies, but should also include the EMA's Committee for Medicinal Products for Human Use (CHMP) or the radiopharmaceutical scientific community specifically. The speed at which new targeting molecules, certain radiopharmaceuticals, and AI-assisted theranostic approaches are entering clinical development makes this a matter of regulatory preparedness, not merely of professional recognition.

### b. Regulatory Sandbox Mechanism

The regulatory sandbox mechanism appears well-suited to the development of novel theranostic agents, which often straddle multiple regulatory frameworks (medicinal products, medical devices, radiation protection). To facilitate this mechanism, **Biotech radiopharmaceuticals, including for**

**paediatrics, should be explicitly eligible for cross-framework sandboxes, and radiation protection authorities should be included among the relevant competent authorities engaged in sandbox design.** Such regulatory sandboxes should also facilitate the evaluation of new imaging techniques, dosimetry methodologies and AI-assisted treatment planning approaches in radiopharmaceutical development.

### c. EU Health Biotechnology Support Network

The Act establishes an EU Health Biotechnology Support Network with functions including assisting developers in identifying regulatory pathways, supporting SMEs and academic start-ups, and providing access to clinical/hospital settings, including for paediatric patients. This Network has the potential to support academic nuclear medicine departments developing novel radiopharmaceuticals. However, since the focus is on biologicals and ATMPs, **it should be specified that the Network's mandate explicitly covers radiopharmaceutical developers, including academic nuclear medicine departments conducting research, and that it should include nuclear medicine expertise in its membership or advisory capacity.**

## 6. Amendments to the Clinical Trials Regulation (Chapter IX)

Increasing global competition in biotechnology and clinical research highlights the need for coordinated EU action to increase Europe's attractiveness for radiopharmaceutical clinical trials. Countries including the United States, China, and Australia are actively developing innovation-friendly clinical trial procedures through simplified communication with authorities, flexible early research pathways, and workable multicentre trial procedures. **Ensuring that the EU remains competitive for radiopharmaceutical clinical development is essential to support innovation, facilitate medical work, and enable patient access to advanced nuclear medicine diagnostics and therapies.**

The introduction of a new category of "minimal-intervention clinical trials" (MICTs) and the recognition of "low-intervention clinical trials" (LICTs) represent an important step toward aligning regulatory requirements with actual patient risk. **The European Biotech Act rightly acknowledges that non-commercial sponsors conduct most low- and minimal-intervention trials and should benefit from simplified regulatory requirements.** This is especially relevant for nuclear medicine, where academic institutions and hospitals play a central role in clinical research. However, the current proposal lacks sufficiently concrete mechanisms and definitions to operationalize this risk-based approach in practice. Without further clarification, there is a risk that nuclear medicine studies – despite being inherently low-risk – will continue to face disproportionate regulatory burdens, which disincentivises the development of innovative treatments for patients.

Despite the Biotech Act's stated objective to simplify low-risk clinical research, the current proposal presents regulatory gaps:

- The definitions of LICTs and MICTs remain insufficiently clear for real-world clinical practice, including imaging-based studies.
- The text relies on non-binding language (e.g. "requirements may be adapted"), creating uncertainty.
- There is no clear, harmonised pathway ensuring that low-risk trials benefit from simplified procedures.
- There are significant barriers to conducting multinational trials which are not sufficiently addressed.



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- The fact that nuclear medicine clinical trials need to adhere also to radiation protection rules in accordance with the EURATOM framework is not acknowledged.

These gaps are particularly problematic for nuclear medicine, where a large proportion of studies should logically fall under simplified pathways, and for which studies already have an additional layer of regulation due to radiation protection requirement.

### a. Tailoring the definition of minimal-intervention and low-intervention clinical trials to radiopharmaceuticals

Nuclear medicine imaging studies often involve a single or small number of administrations of an established radiotracer class, at diagnostic doses, with a well-characterised safety profile, meaning they:

- do not introduce new pharmacological risks,
- do not significantly deviate from clinical routine, and
- impose minimal additional burden on patients.

These features clearly align with the intended scope of low- and minimal-intervention clinical trials. Nevertheless, under the current regulatory framework, such studies are often subject to full clinical trial authorisation procedures, resulting in delays in trial initiation, increased administrative costs, and reduced feasibility of multicentre academic studies.

**To ensure these studies can benefit from the reduced administrative requirements applied to minimal- and low-intervention clinical trials, the definitions should explicitly include studies where:**

- **the investigational radiopharmaceutical is authorized,**
- **it is used within established clinical practice or evidence-based protocols, and**
- **additional procedures do not exceed minimal risk compared to routine care.**

For paediatrics specifically, EANM-validated paediatric dosage card[ix] and international professional guidelines should be recognised as qualifying evidence of evidence-based use for the purposes of LICT classification.

### b. Establishing a unified, simplified regulatory pathway

The regulatory pathway for authorization should be further harmonized for both LICTs and MICTs:[x]

- Ethics Committee approval should be sufficient for trial initiation
- Additional regulatory authorization should not be required for low-risk studies
- Procedures should be standardized across Member States

### c. Implementing risk-proportionate safety requirements

We welcome the proposed amendment simplifying adverse event reporting for minimal- and low-intervention trials, because a **risk-based approach to safety reporting** is entirely appropriate for nuclear medicine imaging studies and encourages the development of innovative treatments. In addition, the **reporting of adverse events in diagnostic studies should be simplified**, which maintains patient safety while eliminating unnecessary administrative burdens.



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### d. Enabling efficient multinational imaging trials

Obtaining approval for multicentre and multinational clinical trials is often very difficult, both within one country with work being performed in separate institutes, or between countries. This applies even when tracer safety etc. has been previously clinically shown and with ethics approval having been obtained. **To support high-quality evidence generation, the framework should facilitate the use of harmonized EU templates, a single core dossier for radiopharmaceuticals and coordinated assessments led by a reporting Member State.** This is essential for multicentre nuclear medicine trials, particularly in rare diseases and oncology, where equal patient access is otherwise impossible.

It is important that the harmonisation objectives of the Clinical Trials Regulation are functioning in practice, so that coordinated assessment procedures effectively facilitate multinational EU clinical trials. For radiopharmaceutical trials in particular, significant national divergences continue to create administrative burdens and delays, including differences in radiation protection requirements, repeated good manufacturing practices inspections and quality audits, and duplicative reassessments by national competent authorities. **Greater convergence and mutual recognition mechanisms would support more efficient cross-border clinical development of radiopharmaceuticals within the EU.**

### e. Harmonising clinical trial methodologies for radiopharmaceuticals

In addition to administrative harmonisation, there should also be harmonisation of technical and practical procedures to support standardised imaging acquisition protocols, quantitative imaging procedures, activity quantification, radiation risk assessments, patient release criteria, radioactive waste handling, and dosimetry methodologies / reporting across Member States. Harmonising such approaches would contribute to innovation, patient safety and regulatory convergence across the EU.

### f. Considering the relevance of EURATOM legislation

Nuclear medicine must comply with legislation such as the EURATOM Directive alongside the CTR, including requiring justification of the research exposure, optimisation of the process, and compliance with national limits. These requirements intersect directly with the CTR framework but are not acknowledged in the Biotech Act. The absence creates a legislative blind spot in which the Biotech Act accelerates clinical trial authorisation without addressing the additional regulatory layer imposed by radiation protection law. **Therefore, there should be a cross-reference explicitly acknowledging the applicability of the EURATOM Directive to clinical research involving ionising radiation and requiring that the streamlined CTR procedures shall apply without prejudice to, and in coordination with, EURATOM research exposure authorisation requirements.**

Implementing provisions should further ensure appropriate coordination between CTR authorisation timelines and mandatory radiation protection assessments required under national Euratom transposition legislation for research exposures involving minors, including, where necessary, proportionate timeline adaptations, in order to avoid procedural uncertainty and unnecessary delays in trial initiation.

When applying the legislation or drafting guidelines, it should be made clear that radiation doses within EURATOM-mandated limits for research subjects, including minors, do not per se constitute grounds for refusing authorisation of nuclear medicine trials.

### g. Enabling interoperable health data frameworks

Allowing application dossiers to rely on health data from the EHDS is potentially beneficial for nuclear medicine, where imaging data from existing clinical studies could support trial applications. However, nuclear medicine imaging data (DICOM-PET/SPECT datasets, dosimetry records) present specific technical challenges for EHDS interoperability that must be considered when implementing the EHDS/CTR interface and defining interoperability standards for this data type.

### h. Promoting innovation and simplify the use of AI tools in clinical trials

Many radiopharmaceutical clinical trials use research-grade AI tools for lesion segmentation[xi], endpoint adjudication[xii], or biomarker quantification[xiii] that are not CE-marked under the Medical Device Regulation (MDR) and are not intended for market placement. While some of these systems may still fall within the scope of MDR investigational-device provisions where they influence clinical decision-making or trial endpoints, they are not subject to full conformity assessment requirements compared to market-placed medical devices. This creates a regulatory grey zone in which research-grade AI used in trial endpoints operates without harmonised expectations on traceability, version control, or reproducibility. **The European Medicines Agency, in coordination with the AI Office and national competent authorities, should issue specific guidance on the use, traceability, version control, and reproducibility of non-CE-marked research AI tools in clinical trial endpoints.**

## 7. Conclusions

**Nuclear medicine is a European success story.** The EU is home to world-leading expertise in radiopharmaceutical development, cyclotron infrastructure, and theranostic innovation, and the field is expanding rapidly in response to unmet clinical needs, particularly in paediatric oncology and rare diseases. **The Biotech Act has the potential to consolidate and accelerate this leadership. However, in its current form, the Act risks inadvertently disadvantaging the very sector it should be strengthening, by failing to account for the specific regulatory, technical, and infrastructural characteristics of radiopharmaceuticals and nuclear medicine.**

The EANM stands ready to provide technical assistance to the Commission, the European Parliament, and the Council throughout the legislative process, and to contribute to the development of implementing measures and guidance that will determine whether the Act's ambitions are realised in clinical practice. **The nuclear medicine community's goal is a Biotech Act that is genuinely fit for purpose across all areas of health biotechnology innovation, including those that deliver the most direct benefit to patients with the fewest therapeutic alternatives.**

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[i] Holzwarth U W, Cirillo R, Goulart M, et 2025) Anticipating the surge: Limited treatment capacities may challenge access of cancer patients to radioligand therapy. Preprint available at SSRN: https://ssrn.com/abstract=5747163.

[ii] Radioligand therapies are made up of a ligand, which can target and bind to cancer cells, and a radioisotope, which emits therapeutic radiation to kill these cells. It can be applied to many cancers, such as neuroendocrine tumours, including thyroid and prostate cancer and lymphoma.

[iii] More information on nuclear medicine and the challenges it faces can be found in the EANM Overarching Narrative.

[iv] Theranostics is a term derived from a combination of therapeutics and diagnostics. It is used in Nuclear Medicine to describe the possibility of both diagnosing and treating a disease with the same chemical structure to ensure best patient outcome.

[v] Radionuclide therapy is a systemic and targeted therapy which uses unsealed radioactive sources.

[vi] Radioisotopes are radioactive isotopes of a chemical element, i.e. 'versions' of an atom which share the same number of protons, but not of neutrons, as their stable, non-radioactive counterparts, thereby providing them with the capacity to lose their energy by radiation (radioactivity). Radioisotopes are produced in nuclear reactors, cyclotrons or generators. They are used to produce radiopharmaceuticals: the most common radioisotope used in Nuclear Medicine is technetium-99m (Tc-99m).

[vii] Positron emission tomography (PET) is a Nuclear Medicine procedure utilising positrons to depict body-internal biological processes – the imaging procedure resulting in the so-called PET scan of the patient. Also, commonly referring to the device/machine that is used to produce these scans. The use of PET and SPECT depends on the kind of particle/radiation emitted by the radioisotope.

[viii] Single photon emission computed tomography (SPECT) is a Nuclear Medicine procedure using single photons to depict body-internal biological processes – the imaging procedure resulting in the so-called SPECT scan of the patient. Also, commonly used to refer to the device/machine that is employed to produce these scans.

[ix] See here: https://eanm.org/publications/useful-resources/dosage-card/

[x] More information on nuclear medicine's challenges and possible solutions can be found in the EANM Overarching Narrative.

[xi] Lesion segmentation refers to the automated identification and delineation of abnormal tissue areas (such as tumours or metastases) within medical images, enabling reproducible measurement of lesion size, volume and distribution across imaging time points.

[xii] Endpoint adjudication is the standardised and often blinded evaluation of clinical trial outcomes, such as tumour response or disease progression, against pre-defined criteria. It ensures consistent and objective classification of results across trial sites.

[xiii] Biomarker quantification refers to the automated measurement of biological signals derived from imaging or other data sources, such as tracer uptake or metabolic activity. It serves as an objective and measurable indicator of disease status, treatment response or physiological function.



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